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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,525	11/29/2001	Erlinda M. Gordon	EPE1110-1	6086

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FISH & RICHARDSON, PC  
12390 EL CAMINO REAL  
SAN DIEGO, CA 92130-2081

EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/997,525

Applicant(s)

GORDON ET AL.

Examiner

Ram R. Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 6 and 9-26 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 11-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 9, 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other. \_\_\_\_\_

Art Unit: 1632

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/25/04 has been entered.
2. Claims 2, 4-5 and 7-8 have been cancelled.
3. Applicant's election without traverse of the invention of group I, claims 1, 3 and 9, 10 in Paper No. 12 (4/25/03) is reiterated.
1. Claims 1, 3, 9-26 are pending.
2. Regarding claims 23-26 it is noted that these claims were presented in the amendment filed 2/17/04. These claims were drawn to the invention of group III, a method of treatment comprising administering a composition of two vectors. Accordingly, these claims have not been considered.
3. Claims 6 and 11-26 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12 (4/25/03).
4. Claims 1, 3 and 9-10 are under consideration.

### *Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (WO 98/44938, 15 October 1998).

Art Unit: 1632

This art teaches a retroviral particle wherein the viral surface protein has been modified to include a targeting polypeptide that binds to an extracellular matrix component of a cell and the particle also comprises a therapeutic gene. The extracellular component of the cell may be a collagen and the binding domain may be a collagen-binding domain such as present in Von Willebrand collagen factor (see the description on page 7). The therapeutic gene present in the vector can be any gene, such as a cytokine, including GM-CSF. The art also teaches method of delivering therapeutic genes to tumor and a method of treatment (see the entire disclosure including that on pages 7, 15, 20-22, examples, and claims, for example, claims 17, 18).

Therefore, Hall et al anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 3, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al<sup>1</sup> (W0 98/44938, 10-15-1998) or Hall et al<sup>2</sup> (Human Gene Therapy 11:983-993, 2000) or Liu et al (Journal of Virology 74:5320-5328, 2000) or Gordon et al (Cancer Research 60:3343-3347, 2000) in view of Kurane et al (Annals of Surgery 4:579-585, 1997) and Borrello et al (Human Gene Therapy 10:1983-1991, 1999) for reasons of record set forth in the previous office action of 8/21/03 and 5/18/04.

### ***Response to Arguments***

Applicant's arguments filed 10/18/04 have been fully considered but they are not persuasive. Applicants argue that for prima facie case of obviousness some reasonable expectation of success is required. However, applicants have not provided why by following the method taught by the cited art an artisan could not have reasonable expectation of success of practicing the claimed invention. Applicants' then use the enablement rejection in the office action of 8/21/03 to argue that in vivo gene transfer is unpredictable. However, this rejection

Art Unit: 1632

was withdrawn in view of applicants' arguments. It seems like applicants are trying to argue that the invention is enabled when it is in their interest and then it is not enabled when it is in their interest. Since the applicants have argued that the art of in vivo gene expression is enabled as pertaining to claims under consideration and the rejection has been withdrawn, applicants cannot use the examiner's reasonings in the support of their own arguments. If applicants are accepting on record that in vivo gene expression is not enabled as discussed in the previous office action of 8/21/093, the enablement rejection will be reinstated.

With regards to applicants' arguments in the first full paragraph on page 7 of their argument, it is noted that applicants have argued about method which is only claim 10. Claims 1, 3, 6 and 9 are drawn to a composition of a vector and applicants have not provided any evidence why an artisan of ordinary skill could not make the claimed vector with reasonable expectation of success. Applicants' arguments in the second paragraph that Kurane does not teach how to use cytokine in gene therapy is again irrelevant because claims 1, 3, 6 and 9 are drawn to a composition, not a method of gene therapy. Applicants seem to ignore the fact that Hall et al teaches targeting vectors and using these vectors for gene therapy and one of the genes that could be delivered using Hall's vector is GM-CSF (see pages 7, 15-18, 20-22). Applicants have not provided any guidance as to why it would require undue experimentation to make the vector (claims 1, 3, 6 and 9) and practice the method of claim 10 by following the teachings of the cited arts. Applicants arguments that expression of GM-CSF at tumor locations resulted in reduced tumor mass. Again these arguments are irrelevant to the vector claims. Next, applicants have argued of un-expected result of recruitment of host mononuclear cells to the site of tumor. It is noted that this result is irrelevant to the instantly presented claims because no such limitation is recited in the claims. In conclusion, applicants' arguments are not persuasive to obviate the rejections of record and the rejections are maintained.

### ***Conclusion***

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR

Art Unit: 1632

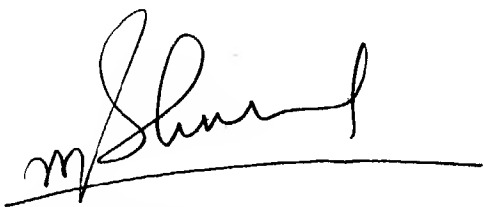
1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (571) 273-8300. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (571) 272-0532.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632



RAM R. SHUKLA, PH.D.  
PRIMARY EXAMINER